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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/200,657	11/25/98	HEIN M	TSRI-184.2C0

HM22/1012

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EXAMINER	
BUI, P	
ART UNIT	**PAPER NUMBER**
1638	15

DATE MAILED: 10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/200,657	Hein et al.
Examiner	**Group Art Unit**
Phuong Bui	1638

☒ Responsive to communication(s) filed on *Jun 8, 1900*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21 and 32-78* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21 and 32-78* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 8, 2000 has been entered. Claims 21 and 32-78 are pending and are examined in the instant application. A new Office action having new grounds of rejection is set forth below. of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the specification. Specifically, parent priority application 08/642406, now US Pat. No. 5,959,177, should also be included as appropriate. The recitation of "the disclosures of which are incorporated by reference herein" should be deleted because such incorporation may constitute new matter.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 13, filed June 8, 2000 (identical to IDS submission of March 24, 2000) is attached to the instant Office action.

The During reference is considered only to the extent of the submitted English translation, which does not appear to be a complete translation of its German counterpart.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Double patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21 and 32-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-30 and 36-37 of copending Application No. 09/199534. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application allows for the inclusion of a leader sequence, which was well known in the art, as evidenced by the new prior art rejections below, also see von Heijne (J. Mol. Biol., 1985, Vol. 184, p. 99-105 (U)). Furthermore, it would have been obvious to utilize the methods set forth in claims 36-37 of the

09/199534 application to make the claimed product since the method simply introduced the nucleotides containing the gene of interest into the claimed transgenic plant, and thus would not be patentably distinct from the transgenic plant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 21 and 32-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-64 of copending Application No. 09/512568. Although the conflicting claims are not identical, they are not patentably distinct from each other because immunoglobulin and antibodies are the prototypic and main species of multimeric proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 21 and 32-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-12 of U.S. Patent No. 5,959,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the genus-species relationship, i.e., the species renders the genus obvious. The scope of the claims of the instant application (genus) fully encompasses the patented claims (species). The heavy chain and/or light chain of the antibody species renders obvious the immunoglobulin and glycopeptide multimers genus. Further, Fab, Fab', F(ab)2, Fv and J chain were well known

antibody components. Thus, the claims of the instant application is rendered obvious by the patented claims.

9. Claims 21 and 32-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because immunoglobulins and antibodies are the prototypic and main species of glycopolypeptide multimeric proteins which are used to induce passive immunity (Abstract and col. 2, ln. 62-64 of the patent). The amount of protein produced appears to be inherent of the plant of 09/200657. The method of making holds little weight in the patentability of the product if the products are identical. Again, antibody components were well known in the prior art (see above rejection).

10. The rejection of claims 21 and 32-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,639,947 has been **obviated** by Applicant's filing of terminal disclaimer received September 13, 1999.

Claim Rejections - 35 USC § 112, second paragraph

11. Claims 42, 55 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 42, "the multimeric protein" lacks antecedence. In claims 55 and 67, the metes and bounds of "one-half of an immunoglobulin molecule" is unclear. If the antibody is set in a "Y" configuration, does Applicant mean the top half, bottom half, left half, or right half? Alternatively, does Applicant mean light chain, heavy chain, or half of each?

Since there is no accepted definition for the above term and it is not clearly defined in Applicant's disclosure, it is suggested that Applicant specify the antibody region(s) being expressed. Clarification and/or correction of the above issues are required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 21, 32-39, 42-47, 49-57, 60-68, 70-75 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by During (Dissertation, July 9, 1988, University of Koln, FRG, English translation (Applicant's IDS)). During teaches a transgenic tobacco plant comprising cells which contain and express nucleotide sequences encoding immunoglobulin heavy and light chains of an anti-NP-IgM antibody, at least one of which contains a leader sequence from the α-amylase gene of barley. The antibody was glycosylated (p. 4 of English translation) and appears to be free of sialic acid residues. The antibody would inherently contain a paratope. Accordingly, During anticipated the claimed invention.

14. Claims 21, 32-40, 42-47, 49-58, 60-68, 70-76 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodman (US Pat. No. 4956282 (previously cited)). Goodman teaches

transformation of monocots and dicots by introducing a vector containing nucleotide sequences encoding immunoglobulin heavy and light chains for expressing immunoglobulins and heterologous leader sequences to direct the expressed product to a particular organelle into plant cells and culturing them (col. 2, ln. 38-40, col. 3, ln. 20-22, ln. 50-54, col. 4, ln. 55-56, col. 5, ln. 34-36). The antibody would inherently possess the Fab, Fab', F(ab)2, Fv and J chain regions, since these are all antibody components. The antibody would inherently possess a paratope. The antibody of Goodman appears to be glycosylated (since Goodman desires retention of its biological activity) and free of sialic acid. Accordingly, absent of evidence to the contrary, Goodman anticipated the claimed invention.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 21 and 32-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over During (Dissertation, July 9, 1988, University of Koln, FRG, English translation (Applicant's IDS)), as applied to claims 21, 32-39, 42-47, 49-57, 60-68, 70-75 and 78 above, and further in view of Applicant's admitted prior art. The teachings of During have been discussed above. While During does not teach transformation of monocots or algae, transformation of these would have been well within the means of one of ordinary skill in the art without any surprising or

unexpected results. It is noted that the examples are directed to transformation of a tobacco and the claims encompass monocots, algae and dicots. Also, while the antibody of During does not have catalytic activity (abzyme), it would have been obvious to transform plants using the method of During to express another desired antibody, such as abzymes of the prior art (specification, p. 30), without any surprising or unexpected results. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transform monocots, algae or dicots, as well as express another antibody including abzymes using the method of During with a reasonable expectation of success.

17. Claims 21 and 32-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman (US Pat. No. 4956282 (previously cited)), as applied to claims 21, 32-40, 42-47, 49-58, 60-68, 70-76 and 78 above, and further in view of Applicant's admitted prior art. The teachings of Goodman have been discussed above. While Goodman does not teach transformation of algae, such transformation would have been well within the means of one of ordinary skill in the art without any surprising or unexpected results. It is noted that the examples are directed to transformation of a tobacco and the claims encompass monocots, algae and dicots. Also, while the antibody of Goodman generically does not have catalytic activity (abzyme), it would have been obvious to transform plants using the method of Goodman to express another desired antibody, such as abzymes of the prior art (specification, p. 30), without any surprising or unexpected results. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transform monocots, algae or dicots, as well as

express another antibody including abzymes using the method of Goodman with a reasonable expectation of success.

Remarks

18. No claim is allowed.

19. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
October 9, 2000

PHUONG T. BUI
PRIMARY EXAMINER

PHUONG T. BUI
PRIMARY EXAMINER